

## **REMARKS**

### **I. Claim Status**

Reconsideration of the present application is respectfully requested. Claims 1 and 33 are currently amended to recite specific antimicrobial compounds, to specify the amount of ethanol, and to more particularly claim the present invention. Support for these amendments is found in the original claims as filed and in the specification at paragraphs [0038], [0045], and Example 10. Claims 10, 14, and 16-30 are cancelled without prejudice. Claims 1-9, 11-13, 15, and 31-34 are pending. No new matter is added by way of this amendment.

### **II. Rejections Under 35 U.S.C. § 103(a)**

U.S. Patent No. 5,985,918 to Modak et al. and U.S. Patent No. 5,965,610 to Modak et al. in view of U.S. Publication No. 2002/0098159 to Wei et al.

Claims 1-9, 11-13, 15, 17 and 31-32 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,985,918 to Modak et al. (hereafter “the ‘918 patent”) and U.S. Patent No. 5,965,610 to Modak et al. (hereafter “the ‘610 patent”), in view of U.S. Publication No. 2002/0098159 to Wei et al. (hereafter “Wei”). The Examiner maintains that the ‘918 patent describes anti-irritant topical formulations comprising water, emollients and two or more organic salts of zinc in a concentration of between 0.1-15%. The Examiner further maintains that the ‘610 patent describes an anti-irritant gel comprising 1-10% zinc gluconate, 1-10% incoquat behenyl TMS, water, emollients and 0.4-4% of an antimicrobial agent such as chlorhexidine gluconate. The Examiner further states that Wei describes topical cream compositions comprising farnesol and antimicrobial agents such as benzalkonium chloride. According to the Examiner, the composition defined by the three references comprises all the elements of the pending claims, rendering the claims obvious.

Applicants respectfully disagree. The claims as amended are not obvious over the cited references when considered separately or in combination. To support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than

predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Furthermore, the claims of the instant application are not obvious over the cited references because practicing the claimed invention produces surprising and unexpected results which a person of ordinary skill in the art would not have predicted in view of the cited references. *See* M.P.E.P. § 716.02(a) and § 2143.02; *see also In re Papeseh*, 315 F.2d 381 (C.C.P.A. 1963).

Applicants respectfully submit that the presently claimed invention is directed to two or more water-soluble, organic salts of zinc, wherein said water-soluble, organic salts of zinc are present in said anti-irritant composition at concentrations between 0.1% and 2% (weight/weight), an antimicrobial compound selected from the group consisting of chlorhexidine gluconate, benzalkonium chloride, and iodopropynylbutyl carbamate, at a concentration of between 0.05% - 4% (weight/weight), 0.05% - 4% (weight/weight) incroquat, water, 60% - 95% ethanol, and one or more agent selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient, and wherein the composition exhibits synergistic preservative effect against bacteria. As amended, the claimed invention is not obvious over the cited references, not only because the combined teaching of the ‘918 patent, the ‘610 patent and Wei fail to disclose all of the elements of the claimed invention, but also that the claimed invention is directed to a composition having unexpected results. Specifically, Applicants submit that the combination of incroquat with chlorhexidine gluconate and benzalkonium chloride unexpectedly and significantly potentiates the preservative effects of the composition as discussed in further detail below.

In the instant office action, the Examiner relies on the ‘918 patent for its disclosure of an anti-irritant topical formulation comprising two or more organic salts of zinc. As contended by the Examiner, the ‘918 patent and the ‘610 patent disclose that zinc salts may be incorporated into compositions at concentrations of between 1-15% or 1-10%, respectively, for reducing irritation. However, Applicants submit that the teachings in the ‘918 patent are limited to compositions that combine zinc salts to reduce irritations caused by a host of irritants. More specifically, the ‘918 patent requires that any composition comprising two or more organic salts of zinc to include zinc salicylate as at least one of the species. *See* the ‘918 patent, Col. 2, lines 27-67. The ‘918 patent fails to provide any basis that combining the zinc salts with additional

constituents would not only maintain the same anti-irritant effect, but that any unexpected synergistic effect would be expected.

Similar to the '918 patent, the '610 patent merely discloses that zinc salts can prevent multiple irritant-inactivating substances from binding to a surface. *See, e.g.*, the '610 patent at Col. 4, line 57 - Col. 6, line 8. Importantly, the '610 patent discloses that in attempting to form a gel-matrix with an antimicrobial agent (*i.e.*, chlorhexidine gluconate), zinc gluconate was the only metal salt that could be formulated with the antimicrobial to successfully produce the gel-matrix, as "other zinc salts mixed with [chlorhexidine gluconate] did not form a gel matrix." *See* the '610 patent at Col. 7, lines 24-37. Thus, because different zinc salts can exhibit different properties with regard to combination formulations, as evidenced by the '610 patent, an artisan of ordinary skill would not have predicted that any zinc salt, let alone two or more zinc salts, could be successfully combined in a single composition with specific antimicrobial agents and incroquat, as recited in the amended claims.

Thus, the '610 patent, like the '918 patent, would have provided no basis for a skilled artisan to predict that the low zinc salt concentrations of the presently claimed invention as combined with specific antimicrobials and incroquat would have a synergistic effect, and as such, the claims as amended are not obvious over the cited references. Applicants respectfully submit that consideration of Wei is moot in view of the claim amendments. Nonetheless, Applicants maintain that Wei does not disclose that any of the agents identified in the reference are compatible with water-soluble organic zinc salts. As the successful combination of zinc salts, antimicrobial agents, incroquat, and other ingredients recited by the claims would not have been predicted by a skilled artisan in view of the cited references, the claims can not be considered obvious in view of the prior art.

The nonobviousness of the presently pending claims is further supported by the surprising and unexpected synergistic antimicrobial effect achieved by combining the elements recited by the claims together in a single composition. As described in Example 10 of the application (*see* pages 47-52), the combination of chlorhexidine gluconate, benzalkonium chloride with incroquat in a single composition resulted in an antimicrobial effect that was greater than the expected additive effect of three compounds. Specifically, a composition comprising chlorhexidine gluconate and benzalkonium chloride exhibited a ten-fold reduction in recovered bacteria compared to a control composition, while a composition containing incroquat

only exhibited a 0.48 fold reduction in bacteria compared to control. When the three agents were combined together in a single composition, a 4-log reduction in bacteria was achieved compared to the control composition. *See* the specification at page 48, paragraph 93; page 48, Table 10; and page 49, Table 11. Thus, there was an expected degree of synergy with the combination of the antimicrobials and incroquat.

The working examples are designed to test what impact additional compounds would have on a specific composition. The instant Example determined the consequences of adding low concentrations of zinc salts to the composition comprising the antimicrobial agents and incroquat. As evidenced by the data in Example 10, the addition of zinc salts did not reduce the antimicrobial effectiveness of the composition. *See* page 50, Table 12. These overall findings confirm the unexpected synergism between incroquat and antimicrobials with low concentrations of zinc salts.

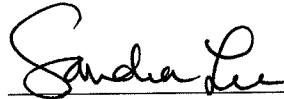
Thus, in view of the cited references' failure to describe all the elements of the claimed invention, in addition to the unexpected reduction of irritation and the synergistic antimicrobial effect achieved by the claimed invention, Applicants submit that the claims as amended can not be deemed obvious over the cited references and respectfully request that the rejections be withdrawn.

### III. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no additional fee aside from the Request for Reconsideration is due at this time. However, if any fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,  
BAKER BOTTS L.L.P.

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